Sheila F. McShane
smcshane@gibbonslaw.com
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500
(973) 639-6482 – Fax

Of Counsel:

Raymond N. Nimrod
Gregory D. Bonifield
raynimrod@quinnemanuel.com
gregbonifield@quinnemanuel.com
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000
(212) 849-7100

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MSD CONSUMER PRODUCTS, INC., SANTARUS, INC., and THE CURATORS OF THE UNIVERSITY OF MISSOURI,	)	
Plaintiffs,	)	
v.	)	C.A. No.3:11-cv-07437 (PGS)(LHG)
ZYDUS PHARMACEUTICALS (USA), INC.,	)	
Defendant.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

MSD Consumer Products, Inc. ("MSD"), Santarus, Inc. ("Santarus"), and

The Curators of the University of Missouri (the "University") (collectively "Plaintiffs") hereby assert the following claims for patent infringement against Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus"), and allege as follows:

THE PARTIES

1. MSD is a corporation organized and existing under the laws of Delaware with its principal place of business at 3030 Jackson Avenue, Memphis, TN 38151. MSD is a subsidiary of Merck & Co., Inc., which has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 3721 Valley Centre Drive, Suite 400, San Diego, California 92130.

3. The University is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, having a place of business at 321 University Hall, Columbia, Missouri 65211.

4. On information and belief, Zydus is a corporation organized and existing under the laws of New Jersey with a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. On information and belief, Zydus is engaged in the manufacturing, marketing and sale of generic pharmaceutical products in the United States, including in the District of New Jersey, and conducts business throughout the United States.

NATURE OF THE ACTION

5. This is a civil action for the infringement of United States Patent No. 7,399,772 ("the Patent-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

7. Zydus is subject to personal jurisdiction in this District because it is incorporated in New Jersey, has its principal place of business in Pennington, New Jersey, conducts business in this District, purposefully avails itself of the rights and benefits of New Jersey law, and has substantial and continuing contacts with New Jersey.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PATENT

9. On July 15, 2008, the PTO issued U.S. Patent No. 7,399,772 (the "'772 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since July 15, 2008, the University has been, and continues to be, the sole owner of the '772 Patent. A copy of the '772 Patent is attached hereto as Exhibit A.

10. Santarus is the exclusive licensee under the Patent-in-Suit for Santarus' ZEGERID brand prescription pharmaceutical products. MSD obtained an exclusive license under the Patent-in-Suit from Santarus for MSD's ZEGERID OTC (omeprazole 20 mg/sodium bicarbonate 1100 mg) Capsules product ("ZEGERID OTC"). Plaintiffs have the right to sue to enforce the Patent-in-Suit.

11. The Patent-in-Suit is listed in the United States Food and Drug Administration's (the "FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly known as the Orange Book, in support of ZEGERID OTC. ZEGERID OTC is marketed by MSD.

12. Santarus and the University previously brought patent infringement lawsuits against Par Pharmaceuticals, Inc. ("Par") for infringement of the Patent-in-Suit, along with other patents, in the United States District Court for the District of Delaware ("Delaware Court"), consolidated as *Santarus, Inc. v. Par Pharmaceutical, Inc.*. CA. No. 07-55 l-GMS ("Delaware Litigation"). After the Delaware Court issued a ruling invalidating certain claims of those patents, including certain claims of the Patent-in-Suit, Santarus and the University filed an appeal of that decision in the United States Court of Appeals for the Federal Circuit, which was assigned Federal Circuit Docket Number 2010-1360 and consolidated with Par's cross-appeal Docket Number 2010-1380 ("Appeal").

13. On September 4, 2012, the Federal Circuit issued its ruling in the Appeal. In that ruling, the Federal Circuit reviewed obviousness *de novo* as a question of law. Slip. Op. at 13. The Federal Circuit then held: "[D]isclosure [in the prior art] would discourage a person of ordinary skill in the art from pursuing conventional oral dosage forms such as tablets, capsules, or granules with non-enteric coated PPIs, and thus teaches away from such formulations. As a result, we hold that the district court erred by concluding that claims directed to such conventional dosage forms would have been obvious over [the prior art]. We thus reverse the court's obviousness holding with respect to claims 4, 5, 8, 10, 12, 14, and 15 of the '772 patent, which all are directed to conventional dosage forms, such as tablet or capsules, containing non-enteric coated PPIs." Slip Op. at 20-21 (emphasis original). A few pages later in its opinion, the Federal Circuit also reversed the Delaware Court's obviousness ruling with respect to claims 20 and 21 of the '772 patent. *Id.* at 24-25. In addition, the Federal Circuit reversed the Delaware Court's ruling that claims 4, 5, 8, 10, 12, 14, 15, 20 and 21 of the '772 patent were invalid for lack of written description. *Id.* at 12-13.

ACTS GIVING RISE TO THIS ACTION

14. On information and belief, on or before November 11, 2011, Zydus submitted Abbreviated New Drug Application No. 203345 (the "Zydus OTC ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Zydus OTC ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a generic omeprazole and sodium bicarbonate capsules, 20 mg/1100 mg (the "Proposed Zydus Capsules"), a generic version of ZEGERID OTC. The Zydus OTC ANDA specifically seeks FDA approval to market the Proposed Zydus Capsules prior to the expiration of the Patent-in Suit.

15. Plaintiffs received a letter dated November 11, 2011, from Zydus notifying them that the Zydus OTC ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Zydus Paragraph IV Certification") that, in Zydus' opinion, the Patent-in-Suit is invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed Zydus Capsules.

16. Plaintiffs commenced this action within 45 days of receiving the Zydus Paragraph IV Certification.

CLAIM FOR RELIEF

INFRINGEMENT OF THE '772 PATENT

17. Plaintiffs incorporate by reference paragraphs 1 through 16.

18. The submission of the Zydus OTC ANDA to the FDA, including the Zydus Paragraph IV Certification, constitutes infringement of the '772 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the

Proposed Zydus Capsules, or any inducement of or contribution to such conduct during the term of the '772 Patent would further infringe the '772 Patent under 35 U.S.C. § 271(a)–(c).

19. Zydus had actual and constructive notice of the '772 Patent prior to filing the Zydus OTC ANDA.

20. Zydus' infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that:

1. Judgment be entered that Zydus has infringed the Patent-in-Suit;

2. Judgment be entered that the commercial use, sale, offer for sale, manufacture, and/or importation by Zydus of the Proposed Zydus Capsules would infringe the Patent-in-Suit;

3. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of the Zydus OTC ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be a date which is not earlier than the expiration date of the Patent-in-Suit, including any extensions;

4. That Zydus, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, or selling the Proposed Zydus Capsules within the United States, or importing the Proposed Zydus Capsules into the United States, prior to the expiration of the Patent-in-Suit, including any extensions;

5. That, particularly in view of the Federal Circuit's decision in the Appeal, the case be found exceptional under 35 U.S.C. § 285 and that Plaintiffs be awarded their attorneys fees; and

6. Such other and further relief as the Court may deem just and proper under the circumstances.

Respectfully submitted,

GIBBONS P.C.

Dated: September 26, 2012
Newark, New Jersey

s/ Sheila F. McShane
By: Sheila F. McShane, Esq.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
Facsimile No.: (973) 596-0545

Of Counsel:

Raymond N. Nimrod
Gregory D. Bonifield
QUINN EMANUEL URQUHART & SULLIVAN, LLP
raynimrod@quinnemanuel.com
gregbonifield@quinnemanuel.com
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000
(212) 849-7100

Attorneys for Plaintiffs MSD Consumer Products, Inc., Santarus, Inc. and The Curators of the University of Missouri